SETTLEMENT APPROVAL ORDER

ACTION NUMBER	1201-12838
COURT	COURT OF KING'S BENCH OF ALBERTA
JUDICIAL CENTRE	CALGARY
PLAINTIFFS	FIONA SINGH and MUZAFFAR HUSSAIN by his litigation representative FIONA SINGH
DEFENDANTS	GLAXOSMITHKLINE INC. GLAXOSMITHKLINE LLC and GLAXOSMITHKLINE PLC.

Brought under the *Class Proceedings Act*, SA 2003, c C-16.5 (the *CPA*)

DOCUMENT	**ORDER**
ADDRESS FOR SERVICE AND CONTACT INFORMATION OF PARTY FILING THIS DOCUMENT	**NAPOLI SHKOLNIK** 1000 – 7 Avenue SW, Suite 400 Calgary, Alberta T2P 5L5 **Clint Docken, K.C. | Casey R. Churko** Tel: (403) 619-3612 Fax: (639) 739-2223

DATE ORDER WAS PRONOUNCED	**September 24th, 2024**
JUDGE WHO MADE THE ORDER	**Hon. Justice EJ Sidnell**

ORDER
(Settlement Approval)

UPON THE APPLICATION of the Plaintiffs:

AND UPON READING:

Schedule 1 – Amended Settlement Agreement, with the following attached:
- Appendix "A" Form of Release for Health Insurers;
- Schedule A – *Notice of Settlement Approval*;
- Schedule B – Notice Plan for *Notice of Settlement Approval*;
- Schedule C – *Settlement Approval Order*;

Schedule D – Distribution Protocol;
Schedule E – Claim Form; and

Schedule 2 – Distribution Protocol and Schedule to Distribution Protocol

All of which documents are attached to this Order as Annex A, and are referred to, collectively, as the *Amended Settlement Agreement*, or individually by name.

AND ON HEARING the submissions of Casey Churko and Clint Docken KC, counsel for the Plaintiffs, E.F. Anthony Merchant, KC, former counsel for the Plaintiffs and of Randy Sutton, counsel for the Defendants;

AND UPON BEING ADVISED that notice of this Settlement Approval Hearing was provided by the Claims Administrator pursuant to the terms of the *Order (Settlement Approval Hearing Notice)* pronounced June 5th, 2024 and filed June 10th, 2024;

AND UPON HAVING CONSIDERED all materials filed and used at the hearing;

AND UPON THE PARTIES AGREEING that the application would proceed only in relation to the settlement of the claim against the Defendants and that the issue of legal costs, fees and disbursements, together with an honorarium for the representative plaintiff, Fiona Singh (the Costs Application), would be addressed at a later; and as such this Order does not approve any of those items notwithstanding that they are contained in various aspects of the *Amended Settlement Agreement*.

IT IS HEREBY ORDERED:

1 Those portions *Amended Settlement Agreement* addressing issue of legal costs, fees and disbursements, together with an honorarium for the representative plaintiff, Fiona Singh, are not approved and are not incorporated by reference into this Order, regardless of their inclusion in Appendix A.

2 Where terms defined in the *Amended Settlement Agreement* are used in this Order, those terms shall have the meanings given them in the *Amended Settlement Agreement*.

3 Subject to any exclusions or variations set out in this Order, the following portions of the *Amended Settlement Agreement* are approved as fair, reasonable, and in the best interests of the Class and are hereby approved and are binding on Class Members, the Releasors, and the

Defendants pursuant to the *CPA*, s 35 and shall be implemented in accordance with their respective:

(a) Schedule 1 – Amended Settlement Agreement, but only the following sections:
    (i) Section 2 (Conditions Precedent to Settlement Approval);
    (ii) Section 4 (Settlement Fund);
    (iii) Section 5 (Notice Provider and Claims Administrator);
    (iv) Section 6 (Objections);
    (v) Section 7 (Releases and Dismissals);
    (vi) Section 9 (No Admission of Liability); and
    (vii) Section 10 (General Provisions) of the *Amended Settlement Agreement*; and
    (viii) all of the related definitions set out in the *Amended Settlement Agreement*;

(b) Appendix "A" Form of Release for Health Insurers;

(c) Schedule A – *Notice of Settlement Approval*;

(d) Schedule B – Notice of Plan for *Notice of Settlement Approval*;

(e) Schedule E – Claim Form; and

(f) Schedule 2 – Distribution Protocol and Schedule to Distribution Protocol Appeal from Decision of Claims Administrator/Claims Officer

4 The steps taken by the Notice Provider to notify Class Members of the Settlement Approval Hearing are deemed reasonable and appropriate.

5 The *Notice of Settlement Approval*, in a substantially similar form to that attached as Schedule A – Notice of Settlement Approval, shall be distributed pursuant to Schedule A – Notice of Settlement Approval and such distribution is approved by this Court as being reasonable notice of the settlement and the applicable terms of the *Amended Settlement Agreement* in accordance with the requirements of the *CPA*.

6 The Claims Administrator may be paid up to $180,000 without further Court approval for Administration Costs (excluding its expenses and applicable taxes). If the Administration Costs of the Claims Administrator exceed $180,000 (excluding its expenses and applicable taxes), further amounts may be payable from the Compensation Fund on further application to, and with the approval of, the Court. Any work required of the Claims Administrator that is not part of its core duties in relation to the Distribution Protocol may be billed at the following hourly rates: $150 for

translations; $325 for senior management; $155 for information technology; $155 for project management; and $65 for administrative duties.

7 The Defendants shall have no responsibility or liability, under any circumstances, for any additional or further payments as set out in the *Amended Settlement Agreement*, including in relation to the settlement, Class Proceeding, or discontinuance of any individual actions of the Class Members pertaining to the subject matter of the Class Proceeding.

8 Any and all claims, whether direct, subrogated, or otherwise, that a Releasor or a Health Insurer may otherwise have had against the Releasees, Plaintiffs, or any Class Member, and whether arising by statute, equity, or at law, is hereby and forever released and discharged, and the Releases as outlined in the *Amended Settlement Agreement*, provided by the Releasors and the Health Insurers (to the extent that Health Insurers may release such claims under their respective health care costs recovery legislation), are approved by this Court as being fair and reasonable and shall be binding on Class Members who have not opted out and the Health Insurers.

9 The appointment of Trilogy Class Action Services as the Claims Administrator, whose responsibilities shall include but are not be limited to (a) administering the Distribution Protocol in collaboration with the Claims Officer, (b) accepting and maintaining documents sent from Class Members, including *Claim Forms* and other documents relating to Claims administration, (c) administering the Settlement Fund and Compensatory Payments, and (d) all other responsibilities designated to the Claims Administrator in the *Amended Settlement Agreement*, is hereby approved, except that the Account referred to at section 1.1(a) of the *Amended Settlement Agreement* will be held by Mr. Churko as counsel for the Class instead of by the Claims Administrator until the Claims have been resolved. The Claims Administrator will provide Class Counsel and the Defendants with any information or documents that Class Counsel or the Defendants request concerning the administration of the settlement including details of distribution.

10 The appointment of a Claims Officer, to be agreed to by the Parties or further Order of this Court, and whose responsibilities shall include but not be limited to (a) reviewing medical records of the Claimants, (b) determining whether a Claimant Child was born with a Qualifying Congenital Malformation, (c) identifying the category in the Distribution Protocol applicable to the Qualifying

Congenital Malformation, and (d) assigning a points value within the ranges set out in the Distribution Protocol, is hereby approved.

11 The Claims Deadline shall be 90 days from the publication of the *Notice of Settlement Approval*. A Class Member, whether represented or unrepresented, will be at liberty to apply to the Court to extend the Claims Deadline or the Claims Perfection Deadline for up to 60 days, so long as such application is made before the Claims Deadline or Claims Perfection Deadline and the Class Member provides notice of the application to the Claims Administrator, Class Counsel, and counsel for the Defendants. Such application will be unnecessary if Class Counsel, the Claims Administrator, and counsel for the Defendants each agree to extend the Claims Deadline, and where the Class Member explains the need for the extension to the satisfaction of both Class Counsel and counsel for the Defendants.

12 The determination of the validity of the Claims submitted by Class Members shall be made by the Claims Administrator and may be appealed as outlined in the *Amended Settlement Agreement.* All submissions will be provided to the Defendants.

13 Without affecting the finality of this *Order*, this Court shall retain exclusive continuing jurisdiction over the settlement process and the Parties thereto, including for all matters relating to supervising, administering, implementing, enforcing, and interpreting the *Amended Settlement Agreement* and the Claims, the enforcement of this *Order*, until the settlement referred to therein becomes final and is no longer subject to appeal.

14 The Parties may apply to this Court for further direction, if necessary, in respect of the implementation and administration of the *Amended Settlement Agreement* as provided for in this Order. This Class Proceeding is otherwise dismissed and all the Claims of the Class Members as against the Defendants relating to the Allegations are extinguished upon distribution of the Compensation Fund.

15 The Costs Application will be heard at a one day hearing, plus one day of reading time for the Court, booked by counsel for the Plaintiffs, with notice to all parties who received notice of this settlement application.

Justice E.J. Sidnell

THE HONOURABLE JUSTICE E.J. SIDNELL

SCHEDULE 1 – AMENDED SETTLEMENT AGREEMENT

AMENDED PAXIL® AND PAXIL CR™
NATIONAL CLASS ACTION SETTLEMENT AGREEMENT

WHEREAS the Plaintiffs brought this proceeding under the *Class Proceedings Act*, SA 2003 c C-16.5, and the Honourable Associate Chief Justice J.D. Rooke certified the Class Proceeding by *Order (Class Certification)* pronounced November 17th, 2022 and filed December 19th, 2022;

AND WHEREAS the Defendants appealed all aspects of the *Order (Class Certification)* by *Civil Notice of Appeal*, filed December 16th, 2022, and deny that any Damages are payable and that the Plaintiffs and/or other Class Members are entitled to relief, and have not conceded but deny all liability and believe that they have reasonable defences to the Class Proceeding and the Allegations;

AND WHEREAS the common issues proposed for certification relate to allegations that Paxil® and Paxil CR™ cause or increase the likelihood of certain congenital malformations in children born to women who ingested Paxil® or Paxil CR™ while pregnant, and that the Defendants failed to provide an appropriate warning of that risk during the Class Period;

AND WHEREAS counsel for the Plaintiffs have conducted a thorough analysis of the merits of the Allegations, and have also taken into account the extensive burdens and expense of litigation, including the risks of trial;

AND WHEREAS in consideration of all of the circumstances and after extensive arm's length negotiations, both directly and with the assistance of a mediator, the Parties wish to settle any and all issues between the Defendants and Class Members in any way relating to the Allegations;

AND WHEREAS after their investigation, the Representative Plaintiff and Class Counsel have concluded that this *Settlement Agreement* is fair, reasonable, and in the best interests of the Class;

AND WHEREAS for the purposes of settlement, and contingent on orders by the Court approving the settlement and the terms of this *Settlement Agreement*, the Representative Plaintiff, on her behalf, on behalf of the minor, Muzzafar Hussain, and on behalf of Class Members, has consented to a dismissal of the Class Proceeding against the Defendants and the release of the Defendants from liability in accordance with the terms of this *Settlement Agreement* having been fully advised of the terms of this *Settlement Agreement* and the settlement herein;

AND WHEREAS the Defendants have entered into this *Settlement Agreement* without any admission of liability;

NOW THEREFORE, in consideration of the covenants, agreements, and releases set forth herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, it is agreed by the Parties that the Class Proceeding be settled and dismissed on the following terms and conditions:

Section 1 – Definitions

1.1 For the purposes of this *Settlement Agreement*, including its recitals and schedules, the following definitions apply:

(a) **"Account"** means a special interest bearing trust account under the control of the Claims Administrator at a Schedule 1 chartered Canadian bank into which the Compensation Fund

shall be paid by the Defendants and on which the interest accrued will be added to the Compensation Fund.

(b) **"Administration Costs"** means the costs of giving the *Notice of Certification, Notice of Settlement Approval Hearing,* and the *Notice of Settlement Approval* and the amounts invoiced to administer and distribute the Compensation Fund, including the expenses and professional fees of the Notice Provider, Claims Officer, and the Claims Administrator.

(c) **"Allegations"** means the assertions of fact or law, causes of action, injuries, and damages that were pleaded in the *Amended Amended Statement of Claim*, filed January 9th, 2019.

(d) **"*Certification Order*"** means the *Order (Class Certification)* of the Honorable Associate Chief Justice Rooke, pronounced November 17th, 2022 and filed December 19th, 2022.

(e) **"Claim"** means the claim made by a Claimant in accordance with the procedure in the Distribution Protocol, which is attached hereto as **Schedule "D"**.

(f) **"Claimant Child"** means a Class Member who was born with a Qualifying Congenital Malformation, or his or her estate or legal representative, who files a Claim pursuant to the terms hereof.

(g) **"Claimant Mother"** means a Class Member who was prescribed Paxil® or Paxil CR™ in Canada and subsequently aborted, delivered, or miscarried children with Qualifying Congenital Malformations after ingesting Paxil® or Paxil CR™ while pregnant, or her estate or legal representative, who files a Claim pursuant to the terms hereof.

(h) **"Claims Administrator"** means Trilogy Class Action Services, the person or entity agreed to by the Parties and approved by the Court to assist the Claims Officer with the administration of the claims process in accordance with the Distribution Protocol.

(i) **"Claims Deadline"** means 90 days from the publication of the *Notice of Settlement Approval*, unless extended as provided for in the *Settlement Approval Order*.

(j) **"Claims Officer"** means a qualified and independent physician agreed to by the Parties who will determine, *inter alia*: whether a Claimant was born with a Qualifying Congenital Malformation; identify the category in the Distribution Protocol within which each Claim falls; and assign a points value within the range identified in the Distribution Protocol.

(k) **"Claims Perfection Deadline"** means 90 days after the Claims Deadline.

(l) **"Class"** means women who were prescribed Paxil® or Paxil CR™ in Canada and subsequently aborted, delivered, or miscarried children with congenital malformations after ingesting Paxil® or Paxil CR™ while pregnant; family members who may make claims under *Family Compensation Legislation* following the death of, or injury in relation to the congenital malformations; children born alive to such women; and provincial and territorial governments who paid health care costs on their behalf.

(m) **"Class Counsel"** means

(i) Casey R. Churko, practicing through KoT Law Professional Corporation; and

(ii) Clint Docken, K.C., practicing through Clint Docken Professional Corporation.

(n) **"Class Counsel Disbursements"** means the agreed amount of legitimate and reasonable disbursements incurred by or at the request of Class Counsel and Former Class Counsel

between the filing of this Class Proceeding (and no other class action or class proceeding filed anywhere in Canada at any time relating to the prescription or use of Paxil®, Paxil CR™, or paroxetine) and the Effective Date; except that the disbursements that may be claimed by Former Class Counsel shall further be limited to those incurred before April 12th, 2019, being the date that the Plaintiffs served a *Notice of Change of Representation*. The amount of disbursements as agreed to is: $175,000 for Napoli Shkolnik Canada; and $175,000 for Merchant Law Group LLP.

(o) **"Class Counsel Fees"** is CDN $2,000,000, separate and apart from Lawyers' Fees, to be paid as follows:

(i) $850,000, to be paid to KoT Law Professional Corporation;

(ii) $50,000, to be paid to Clint Docken Professional Corporation; and

(iii) $1,100,000, to be paid to Former Class Counsel in full and final satisfaction of the undertaking that the Honourable Associate Chief Justice J.D. Rooke referenced at ¶38 of *Singh v Glaxosmithkline Inc.*, 2021 ABQB 316.

(p) **"Class Member"** means any person, or his/her estate or legal representative, who is a member of the Class and did not deliver an *Opt-Out Form* to the Notice Provider on or before April 8th, 2024.

(q) **"Class Period"** means the period that runs from January 1st, 1993 to April 8th, 2024.

(r) **"Class Proceeding"** means the proceeding commenced by Muzzafar Hussain, by his Mother and Litigation Guardian, Fiona Singh, and the said Fiona Singh, in the Court of King's Bench of Alberta against the Defendants (Court File No. 1201-12838), and that was certified as a class proceeding by the *Certification Order*.

(s) **"Compensation Fund"** means the Settlement Fund after deducting: Administration Costs incurred before the *Settlement Approval Order* is made; $525,000 to resolve Health Insurer Claims; the Class Counsel Fees and Class Counsel Disbursements and applicable taxes thereon; and the Honorarium; and after adding the interest while the Settlement Fund is held in the Account. After deductions, the Administration Costs incurred after the *Settlement Approval Order* and Compensatory Payments will be fully paid from the remainder of the Compensation Fund.

(t) **"Compensatory Payments"** means the amounts that are allocated to Eligible Claimants out of the Compensation Fund, including the amounts allocated for Lawyers' Fees.

(u) **"Court"** means the Court of King's Bench of Alberta.

(v) **"Court Approval Date"** means the later of September 24th, 2024 and the date on which the Court approves the *Settlement Agreement*.

(w) **"Damages**" means all claims for pain and suffering, loss of guidance, care and companionship, non-pecuniary claims, in trust claims, subrogated claims (in the form of claims of Health Insurers and non-governmental insurers), past and future income loss claims, past and future care claims, aggravated or punitive damages, and special damages.

(x) **"Distribution Protocol"** means the plan setting out a Class Member's entitlement to make a Claim under this *Settlement Agreement* and how Compensatory Payments to Eligible Claimants and Lawyers' Fees shall be determined and distributed, as approved by the

Court as part of the Settlement Approval Hearing, a draft of which is attached hereto as **Schedule "D"**.

(y) "**Effective Date**" means the later of:

(i) 60 days after the Court Approval Date if there is no appeal from the *Settlement Approval Order*; and

(ii) the date on which any appeals from the *Settlement Approval Order* have been quashed or finally disposed of.

(z) **"Eligible Claimant"** means a Claimant, or his or her estate representative, who has satisfied the Claims Officer that he or she is a Class Member who is eligible for a Compensatory Payment, and, in particular that:

(i) the Claimant Mother or the biological mother of a Claimant Child was prescribed Paxil® or Paxil CR™ for use during her First Trimester of pregnancy;

(ii) the Claimant Mother or the biological mother of a Claimant Child took Paxil® or Paxil CR™ during the Class Period while in her First Trimester of pregnancy who delivered a Claimant Child, born alive, who has been diagnosed with one or more Qualifying Congenital Malformations; and

(iii) there is a medical or other reliable record or affidavit indicating that (1) a physician determined that the Claimant Child had or has one or more Qualifying Congenital Malformations, and (2) the biological mother of the Claimant Child took Paxil® or Paxil CR™ (and not generic paroxetine) during her First Trimester of pregnancy.

Further information with respect to eligibility is contained within the Distribution Protocol.

(aa) **"First Trimester"** means the first 13 weeks of pregnancy calculated from the date of the last menstrual period.

(bb) **"Former Class Counsel"** means E.F. Anthony Merchant, K.C. of Merchant Law Group LLP (being Class Counsel before April 12th, 2019).

(cc) **"Health Insurers"** means all of the provincial and territorial ministries of health or governmental bodies that provide publicly funded plans of health care in Canada.

(dd) **"Health Insurer Claims"** means the entitlement of the Health Insurers to any subrogated or direct claims arising from the provision of health care services to Class Members in relation to the Allegations, and pursuant to legislation that permits the recovery of health care costs or medical expenses from third parties.

(ee) **"Honorarium"** means the amount of CDN $50,000.

(ff) **"Lawyers' Fees"** are, subject to section 8.5, up to 35% of Compensatory Payments paid to Eligible Claimants who are represented by Class Counsel or another lawyer of their choosing who has a valid and enforceable retainer agreement with an Eligible Claimant. Lawyers' Fees paid to lawyers other than Class Counsel shall not exceed 25% where the retainers were executed before the *Notice of Settlement Approval Hearing* is given and 10% where the retainers were executed after. Class Counsel will receive 15% of Compensatory Payments that are made to Eligible Claimants who are unrepresented.

(gg) **"Notice Provider"** means Trilogy Class Action Services, who provided the *Notice of Certification* and the *Notice of Settlement Approval Hearing* and will provide the *Notice of Settlement Approval*.

(hh) **"*Notice of Certification*"** means the form of notice, approved by the Court on February 8th, 2024 that informed Class Members of certification of the Class Proceeding.

(ii) **"*Notice of Settlement Approval"*** means the form of notice, agreed to by the Parties and approved by the Court, and to be given within 30 days of the Court Approval Date, that informs Class Members, including Health Insurers, of the approval of this *Settlement Agreement*, the process for making Claims, and the Distribution Protocol, a draft of which is attached hereto as **Schedule "A"**.

(jj) **"*Notice of Settlement Approval Hearing*"** means the form of notice, approved by the Court as Schedule 1 to the *Order (Settlement Approval Hearing Notice)* pronounced June 5th, 2024 and filed June 10th, 2024, that informed Class Members, including Health Insurers, of the Settlement Approval Hearing.

(kk) **"Notice Plan for *Notice of Settlement Approval*"** is the means used for giving the *Notice of Settlement Approval*, attached hereto as **Schedule "B"**.

(ll) **"*Opt-Out Form*"** means the form approved by the Court as Schedule 2 to the *Order (Certification Notice*), pronounced February 8th, 2024 and filed February 9th, 2024.

(mm) **"Parties"** means the Representative Plaintiff and the Defendants.

(nn) **"Qualifying Congenital Malformations"** as defined include only the following structural congenital malformations (birth defects):

(i) anencephaly;
(ii) spina bifida;
(iii) encephalocele;
(iv) craniosynostosis;
(v) cleft lip;
(vi) cleft palate;
(vii) structural cardiovascular defects;
(viii) diaphragmatic hernia;
(ix) gastroschisis;
(x) omphalocele;
(xi) hypospadias;
(xii) undescended testes; and
(xiii) club foot.

(oo) **"Released Claims"** means any and all claims, demands, actions, suits, causes of action, whether class, individual, or otherwise in nature, whether personal or subrogated, whenever incurred for liabilities of any nature whatsoever, including without limitation claims, demands, actions, suits or causes of action for personal injuries, general damages, special damages, punitive damages, interest, costs, expenses, penalties, and lawyers' fees, whether such claims, demands, actions, suits or causes of action are known or unknown, suspected or unsuspected, arise in law, under statute or in equity, that the Plaintiffs, the Releasors, Class Members (excluding provincial and territorial governments who paid health care costs, which released claims are as specified in Appendix A), or any of them, whether directly, indirectly, derivatively, or in any other capacity, ever had, now have, or hereafter can, shall, or may have relating directly or indirectly, to the production, manufacture, design, sale, marketing, advertising, sale, possession, handling, ingestion,

exposure, or use of Paxil® or Paxil CR™ as they relate to the conduct of the proceedings or in any other manner whatsoever to the Allegations.

(pp) **"Releasees"** means, jointly and severally, the Defendants, GlaxoSmithKline Inc., GlaxoSmithKline LLC, and GlaxoSmithKline PLC, and their respective present and former parents, subsidiaries, affiliates, officers, directors, employees, insurers, agents, attorneys, servants, representatives, and the successors, predecessors, heirs, executors, administrators, trustees, and assigns of each of the foregoing as well as anyone involved in the distribution, prescription or dispensation of Paxil® or Paxil CR™ to the Class Member and it is agreed that to the extent that a Releasee is not a Party to the *Settlement Agreement* all such releases are intended third party beneficiaries of the *Settlement Agreement.*

(qq) **"Releasors"** means, jointly and severally, individually and collectively, the Plaintiffs, Class Members (excluding provincial and territorial governments who paid health care costs), and their respective successors, heirs, executors, insurers, benefits providers, administrators, trustees, and assigns.

(rr) **"Representative Plaintiff"** means Fiona Singh.

(ss) **"*Settlement Agreement*"** means this agreement, as executed by Class Counsel, Former Class Counsel, and counsel for the Defendants on behalf of, respectively, the Representative Plaintiff and the Defendants~~, and by the Health Authorities~~.

(tt) **"Settlement Approval Hearing"** means the hearing at the Court to approve the dismissal of the Class Proceeding, the settlement, and the terms of this *Settlement Agreement* (including its *Schedules*).

(uu) **"*Settlement Approval Order*"** means the Order of the Court approving the dismissal of the Action, the settlement, and the terms of this *Settlement Agreement*, which shall be substantially in the form attached as **Schedule "C"**.

(vv) **"Settlement Fund"** means CDN $7,500,000, and for greater clarity, will be the maximum amount paid by the Defendants in any and all circumstances, as described herein.

(ww) **"Trilogy Invoices"** means the invoices delivered by Trilogy Class Action Services from time to time for services rendered as the Notice Provider and Claims Administrator in the implementation of this *Settlement Agreement*, including for services already provided respecting the *Notice of Certification* and the *Notice of Settlement Approval Hearing*.

Section 2 – Conditions Precedent To Settlement Approval

2.1 This *Settlement Agreement* is subject to and conditional upon Court approval and shall be null and void and of no force or effect if the *Settlement Approval Order* is not granted and sustained on any appeals therefrom.

2.2 Class Counsel shall ensure that, prior to or concurrently with filing the application for approval of the *Settlement Agreement*, that all Health Insurers have been provided with *Notice of the Settlement Approval Hearing*, have been asked to approve the *Settlement Agreement*, and have been asked to agree to sign a release agreeable to the Defendants that is in accordance with each Health Insurers' respective subrogation and/or health care cost recovery legislation. Class Counsel shall also make best efforts to ensure that, prior to the Settlement Approval Hearing, any documentation required by the Health Insurers in relation to the approval of the *Settlement Agreement*, such as but not limited to the *Notice of Proposed Terms of Settlement* pursuant to

Section 13 of the *Health Care Costs Recovery Act* (British Columbia), has been requested from, or completed and provided by, the Health Insurers.

Section 3 – Settlement Approval

3.1 The Parties shall use their best efforts in good faith to effect this *Settlement Agreement*, both before and after it receives Court approval. The Representative Plaintiff shall bring applications seeking approval of: the appointment of the Notice Provider; the appointment of the Claims Administrator; the content and means of giving the *Notice of Settlement Approval*; the Distribution Protocol; and this *Settlement Agreement* and the settlement outlined herein.

3.2 In the event that: (1) the Court declines to approve this *Settlement Agreement* or any part hereof; or (2) the Court order approving this *Settlement Agreement* does not become a final order; then this *Settlement Agreement* shall, unless the Parties agree otherwise, be terminated and, except as provided for herein, it shall be null and void and will have no further force or effect, shall not be binding on the Parties or the Class, and shall not be used as evidence or otherwise in any litigation in accordance with section 9.2 of this *Settlement Agreement*, or disclosed to anyone other than as may be required by law or agreed upon by the Parties.

Section 4 – Settlement Fund

4.1 The Settlement Fund is intended to compensate Class Members in relation to Claims arising from the Allegations, and to pay: the Health Insurer Claims; the Class Counsel Fees, Lawyers' Fees, Class Counsel Disbursements and applicable taxes thereon; the Honorarium; the Administration Costs; and any such further amounts as may be payable in relation to the settlement and Class Proceeding.

4.2 The maximum, all-inclusive payment the Defendants will make, in full and final satisfaction of all claims, costs and expenses, including the Claims of the Plaintiffs, Claims of the Class Members, Health Insurer Claims, Class Counsel Fees and Lawyers' Fees and Class Counsel Disbursements plus applicable taxes thereon, Honorarium, and Administration Costs (which include the Trilogy Invoices), is CDN $7,500,000.

4.3 On the Effective Date, the Defendants shall pay the Settlement Fund to the Claims Administrator in trust. The Defendants shall have no responsibility or liability, under any circumstances, for any additional or further payments under this *Settlement Agreement* or in relation to the settlement and/or Class Proceeding, including as it pertains to any dispute, arisen, arising, or yet to arise, as to the Class Counsel Fees, Class Counsel Disbursements, Lawyers' Fees, the Honorarium, the Trilogy Invoices, Administration Costs, or costs from any action or proceeding relating to the subject matter of the Class Proceeding. In the event that any such dispute arises, the Defendants will be immediately notified of the dispute by Class Counsel, and will have the right, at their option, to participate and make submissions in the determination of that dispute by Court hearing if necessitated.

Section 5 – Notice Provider And Claims Administrator

5.1 Class Counsel has and shall continue to retain Trilogy Class Action Services as the Notice Provider, subject to the approval of the Court.

5.2 Class Counsel shall retain Trilogy Class Action Services as the Claims Administrator, subject to the approval of the Court.

5.3 ~~Class Counsel shall retain a~~ The Claims Officer shall be agreed to by the Parties or be the subject of a further Order of the Court~~, subject to the approval of the Court~~.

5.4 Before the Effective Date, Class Counsel and the Defendants paid or will pay the Notice Provider up to $52,500, which the Parties agree would or will be divided equally between them. Class Counsel agrees and will ensure that the Notice Provider has already or will promptly prepare and deliver corresponding Trilogy Invoices before payment is made. After the Effective Date, the Claims Administrator shall pay the Claims Administrator from the Account:

(i) $77,500 if the number of Eligible Claimants is between 1 and 49,

(ii) $102,500 if the number of Eligible Claimants is between 50 and 74, and

(iii) $127,250 if the number of Eligible Claimants is 75 or more.

All amounts stated in this section are exclusive of applicable taxes and the expenses of the Claims Administrator. Such expenses may be reimbursed to the Claims Administrator from the Account on a dollar-for-dollar basis based on the actual expenses incurred by the Claims Administrator. Such expenses are anticipated to include (but are not limited to) expenses for any long distance phone calls, postage, courier, bank fees, travel, and costs related to maintaining a post office box, toll-free telephone number, and claims portal devoted to the administration of this settlement.

5.5 The Claims Administrator shall receive the Claims of the Claimants provided these are initiated by the Claimants before the Claims Deadline or any extension thereof provided for herein, and shall assist the Claims Officer with the Claims Officer's determination of the amounts of Compensatory Payments and Lawyers' Fees in accordance with the Distribution Protocol.

Section 6 – Objections

6.1 Class Counsel will provide the Health Insurers with formal notice of the proposed settlement as required under applicable subrogation and/or health care costs recovery legislation, in addition to a copy of the *Settlement Agreement*.

6.2 Class Counsel will ensure that any revisions or objections to the *Settlement Agreement* and the terms therein are immediately brought to the attention of counsel for the Defendants.

6.3 A Class Member may object to the approval of this *Settlement Agreement* only by sending a written objection by courier, email, fax, or mail to the Notice Provider. Any objecting Class Member shall provide his or her name, contact information, and a brief statement of the nature and reasons for the objection.

6.4 The Claims Administrator shall report to the Court, by affidavit, with a copy to the Defendants, and provide copies of any objections received prior to the Settlement Approval Hearing.

Section 7 – Releases And Dismissals

7.1 Upon approval by the Court of this *Settlement Agreement*, and in consideration of the payment of the Settlement Fund, and for other valuable consideration set forth in this *Settlement Agreement*, the Releasors will be deemed and hereby expressly agree to forever and absolutely release the Releasees from the Released Claims, and further agree not to make any claim or take, participate in, or continue any proceedings (including a cross claim, third party or other claim) arising out of or relating to the subject matter of the Released Claims against the Releasees and/or any other person, corporation, or entity (including, without limitation, any pharmacists, pharmacies, health care professionals, health care providers, or health care facilities) that might give rise to a claim for damages and/or contribution and indemnity and/or other relief either generally or under the provisions of any provincial or territorial apportionment or contributory negligence legislation, and any amendments thereto, including relief of a monetary, declaratory, or injunctive nature, from one or more of the Releasees.

7.2 The Releases and Dismissals set out herein apply to each Class Member whether or not the Class Member receives compensation under this *Settlement Agreement* as an Eligible Class Member and can be relied on as a defence in any further claim that may be advanced by any Class Member.

7.3 The Representative Plaintiff agrees to make best efforts to obtain through Class Counsel a full and final release of the claims of the Health Insurers in substantially the form attached hereto as **Appendix "A"** and the Releasors undertake to indemnify the Releasees from all awards, recoveries, amounts, costs and expenses incurred on account of any claims, liens, demands, rights, or causes of action by the Health Insurers and/or U.S. Medicare (if applicable) claiming a lien upon, subrogated interest in, or right or entitlement to the proceeds of this settlement, in whole or in part, for any reason, including the provision of medical and/or hospital care and/or the payment of medical and/or hospital expenses by any third party provider/payer, and/or a right to reimbursement or subrogation for any reason arising out of the consideration payable under this *Settlement Agreement*.

7.4 As of the Effective Date, the Class Proceeding shall be dismissed with prejudice and without costs and the Defendants shall abandon their appeal in the Alberta Court of Appeal.

7.5 The Defendants agree to further abandon any claim for costs against any Class Member who has been a plaintiff in any previously filed class action or other proceeding in Canada, and whether costs have been ordered to date or not.

7.6 After the Effective Date, any Class Member who has not opted out, will immediately dismiss on a with prejudice basis any action or proceeding pertaining to recovery relating to the subject matter of the Class Proceedings on a without costs basis, regardless of whether or not compensation is received under this *Settlement Agreement*, including the plaintiffs Megan and Tammy Thompson (Saskatchewan Court of King's Bench (QBG-PA-000276-2019)).

7.7 To the extent such action or proceeding is not dismissed within 30 days of the Effective Date as contemplated in section 7.6, the Plaintiff on behalf of each Class Member, agrees to consent to a dismissal or discontinuance of the action or proceeding at the request of, or on the application of the Defendants, on a with prejudice and without costs basis and to pay the legal costs associated with the steps taken by the Defendants.

Section 8 – Legal Fees

8.1 Class Counsel may bring applications at the Settlement Approval Hearing or on a subsequent date for Court approval of payment of the Class Counsel Fees and Class Counsel Disbursements and applicable taxes thereon. Notice of such a hearing will be provided to the Defendants. The Defendants will not oppose any applications for approval of the Class Counsel Fees, Class Counsel Disbursements, Honorarium, and Lawyers' Fees, insofar as any such applications are not contrary to the terms of this *Settlement Agreement*.

8.2 Class Counsel and other lawyers retained by an Eligible Claimant may charge Lawyers' Fees as a percentage of the Compensatory Payments paid to an Eligible Claimant that they represent after the determination of the Compensatory Payment by the Claims Officer, plus disbursements and applicable taxes, but subject to the limits provided for in section 8.5.

8.3 The amount of the Lawyers' Fees shall not exceed 35% of the Compensatory Payment allocated to any Class Member who is represented, subject to the limits provided for in section 8.5. For any Eligible Claimants who are unrepresented, Lawyers' Fees will be 15% of the Compensatory Payments to the Eligible Claimant.

8.4 The Claims Administrator shall pay each lawyer of Class Counsel and Former Class Counsel their respective shares of the Class Counsel Fees within 7 days of the Effective Date, and Lawyers'

Fees plus disbursements and applicable taxes directly to Class Counsel and other lawyers retained by Eligible Claimants when payments are made to Eligible Claimants.

8.5 Notwithstanding any other provision of this *Settlement Agreement*, the aggregate amount of the Class Counsel Fees and Lawyers' Fees (including disbursements and taxes on Lawyers' Fees but not Class Counsel Fees) shall not exceed 33.33% of the Settlement Fund plus interest thereon, and the amount of the Class Counsel Fees shall not be less nor more than $2,000,000 plus GST.

Section 9 – No Admission of Liability

9.1 The Parties agree that whether or not the *Settlement Agreement* is approved by the Court, the *Settlement Agreement* and anything contained herein, and any and all negotiations, documents, discussions, and proceedings associated with the *Settlement Agreement*, and any action taken to carry out the *Settlement Agreement*, shall not be deemed, construed, or interpreted to be an admission of any violation of any statute or law, or of any wrongdoing or liability by the Releasees, or of the truth of any of the claims or allegations made in the Class Proceeding or in any other pleading filed by the Plaintiffs.

9.2 The Parties further agree that whether or not the *Settlement Agreement* is approved by the Court, neither the *Settlement Agreement* nor any document relating to it shall be disclosed as or offered in evidence in any action, claim, or proceeding in any court, agency, arbitration, or tribunal, except to seek Court approval of the *Settlement Agreement* or to give effect to and enforce the provisions of the *Settlement Agreement*.

9.3 The Parties further understand and agree that the Defendants have entered into this *Settlement Agreement* without any admission of liability, and that the *Settlement Agreement* is conditional on the agreement not being used as a precedent or in evidence in any proceedings whatsoever, regardless of venue or jurisdiction, whether between the Defendants and any other person, including by a party, legal counsel, or Class Member involved in this Class Proceeding at any point.

Section 10 – General Provisions

10.1 This *Settlement Agreement* shall be governed, construed, and interpreted in accordance with the laws of Alberta and Canada.

10.2 The Court shall retain exclusive jurisdiction in the implementation and administration of the *Settlement Agreement* and any disputes arising therefrom.

10.3 Class Counsel, the Defendants, or the Claims Administrator may apply to the case management judge in the Class Proceeding for directions in respect of the implementation and administration of this *Settlement Agreement*, including the Distribution Protocol.

10.4 Other than the payments contemplated under this *Settlement Agreement*, the Releasees shall have no responsibility for, and no liability with respect to, the administration of this *Settlement Agreement* and the Compensation Fund.

10.5 This *Settlement Agreement*, including its *Schedules*, constitutes the entire agreement among the Parties, and supersedes any and all prior and contemporaneous understandings, undertakings, negotiations, representations, communications, promises, agreements, agreements in principle, and settlement terms in connection herewith.

10.6 The Parties agree that they have not received or relied on any agreements, representations, or promises other than as contained in this *Settlement Agreement*. None of the Parties shall be bound by any prior obligations, conditions, or representations with respect to the subject matter of this *Settlement Agreement*, unless expressly incorporated herein.

10.7 This *Settlement Agreement* may not be modified or amended except on written consent of all Parties, and any such modification or amendment must be approved by the Court.

10.8 The representations and warranties contained in this *Settlement Agreement* shall survive its execution and implementation.

10.9 This *Settlement Agreement* may be executed in counterparts, all of which taken together will be deemed to constitute one and the same agreement, and an email or facsimile signature shall be deemed an original signature for purposes of executing this *Settlement Agreement*. This *Settlement Agreement* may be delivered and is fully enforceable in either original, faxed, or other electronic form provided that it is duly executed.

10.10 This *Settlement Agreement* has been the subject of negotiations, mediation, and further discussions among the Parties, each of which has been represented and advised by competent counsel, so that any statute, case law, or rule of interpretation or construction that would or might cause any provision to be construed against the drafter of this *Settlement Agreement* shall have no force and effect.

10.11 The Parties further agree that the language contained or not contained in previous drafts of this *Settlement Agreement*, or any agreement in principle, shall have no bearing upon the proper interpretation of this *Settlement Agreement*.

10.12 Class Counsel shall not publish on their website, or otherwise distribute, any documents relating to the Class Proceeding (including pleadings, expert reports, and transcripts) other than as may be required to advise of the fact that a settlement has occurred and to administer the approved *Settlement Agreement* in accordance with its terms.

10.13 Class Counsel confirms that all mediation and negotiations, direct or indirect, leading up to this *Settlement Agreement* are confidential and shall not be disclosed to the public by Class Counsel or the Parties themselves.

10.14 The Parties acknowledge that they have required and consented that this *Settlement Agreement* and all related documents be prepared in English and French. *Les parties reconnaissent avoir exigé et consenti à ce que cette Entente de Règlement et Quittance et tous les documents connexes soient rédigés en langue anglaise et francaise*.

10.15 The *Schedules* to this *Settlement Agreement* are as follows:

(a) Schedule A – *Notice of Settlement Approval*
(b) Schedule B – Notice Plan for *Notice of Settlement Approval*
(c) Schedule C – *Settlement Approval Order*
(d) Schedule D – Distribution Protocol
(e) Schedule E – *Claim Form*

10.16 Each of the undersigned represents that he or she is fully authorized to enter into the terms and conditions of, and to execute, this *Settlement Agreement*.

10.17 Where this *Settlement Agreement* requires a Party to provide notice or any other communication or document to another, such notice, communication, or document shall be provided by email, facsimile, or letter by overnight delivery to the representatives for the Party to whom notice is being provided, as identified below:

For the Plaintiffs, Class Counsel:

Napoli Shkolnik Canada
1000 – 7 Avenue SW, Suite 400
Calgary, Alberta
T2P 5L5

Clint Docken K.C. | Casey R. Churko
Tel: (306) 540-2284
Fax: (639) 739-2223
Email: cchurko@napolilaw.com

Former Class Counsel:

Merchant Law Group LLP
2710 17 Ave SE #400
Calgary, Alberta
T2A 0P6

E.F. Anthony Merchant, K.C.
Tel: (403) 237-7777
Fax: (403) 273-9411

Email: tmerchant@merchantlaw.com

For the Defendants:

Norton Rose Fulbright Canada LLP
222 Bay Street
Suite 3000, PO Box 53
Toronto, Ontario
M5K 1E7

Randy Sutton
Tel: (416) 216-4046
Fax: (416) 216-3930
Email: Randy.Sutton@nortonrosefulbright.com

IN WITNESS WHEREOF, each of the signatories, whether personally or by counsel, has caused this *Settlement Agreement* to be executed on her/his/their behalf as follows:

Dated: 2024-09-18

Casey R. Churko, as Class Counsel on behalf of the Plaintiffs

2024-09-18

Dated:

E.F. Anthony Merchant, K.C., as Former Class Counsel

Dated: 18/Sept/2024

Norton Rose Fulbright Canada LLP on behalf of the Defendants

APPENDIX "A"

FORM OF RELEASE FOR HEALTH INSURERS

For and in consideration of the payment certain amounts pursuant to a *Settlement Agreement* between the Parties dated [XX], the sufficiency of which is hereby acknowledged, His Majesty the King in Right of the [PROVINCE/TERRITORY OF ●], as represented by the [HEALTH INSURER ENTITY] (the **Releasor**) does for herself and for her agents hereby remise, release and forever discharge the Defendants, GlaxoSmithKline Inc., GlaxoSmithKline LLC, and GlaxoSmithKline PLC, and their respective present and former parents, subsidiaries, affiliates, officer, directors, employees, insurers, agents, attorney, servants, representatives, and the successors, predecessors, heirs, executors, administrators, trustees, and assigns of each of the foregoing (the **Releasees**) from any and all claims made pursuant to the [LEGISLATION NAME] which the Releasor ever had, now has or could have, for or by reason of or arising out of or in any way connected with personal injuries suffered by any person in [PROVINCE/TERRITORY] born with Qualifying Congenital Malformations (as defined in the *Settlement Agreement*) to a woman who ingested Paxil® or Paxil CR™ while pregnant during the period of January 1, 1993 to [DATE], and their biological mothers, who did not deliver an *Opt-Out Form* on or before April 8th, 2024, and which relate to assertions of fact or law, causes of action, injuries and damages that were pleaded in the Court File No. 1201-12838 filed in the Court of King's Bench of Alberta (Calgary), as amended on January 9th, 2019, (the **Action**) and referred to in the common issues certified by the Honourable Associate Chief Justice Rooke, pronounced November 17th, 2022 and filed December 19th, 2022.

It is further expressly understood and agreed that the payment herein shall not be construed as an admission of liability on the part of the Releasees by whom liability is expressly denied. The Release and the *Settlement Agreement* contain the entire agreement between the Releasor and Releasees, and the terms of the Release are contractual and not a recital.

In witness whereof, I, ● have hereunto set my hand at the [CITY], in the [PROVINCE/TERRITORY], this ● day of ●, 2023 as duly authorized signatory on behalf of His Majesty the King in Right of the [PROVINCE/TERRITORY OF ●], as represented by the [HEALTH INSURER ENTITY].

_____

[signature line]

SCHEDULE A – *Notice of Settlement Approval*

LEGAL NOTICE:
PAXIL® AND PAXIL™ USED IN CANADA DURING PREGNANCY

NOTICE OF SETTLEMENT APPROVAL

A class proceeding, *Singh v GlaxoSmithKline Inc*, Court File No. 1201-12838, commenced in the Alberta Court of King's Bench, was certified regarding the selective serotonin reuptake inhibitor "paroxetine" that GlaxoSmithKline Inc. and certain affiliates ("**GSK**") marketed in Canada under the brand names Paxil® and Paxil CR™. The class proceeding alleged that GSK did not warn physicians and patients in the Canadian Paxil® and Paxil CR™ product monographs that either drug posed a teratogenic risk when used during pregnancy. The allegations in the class proceeding are denied by GSK and have not been proven in court. The parties have agreed to settle the class proceeding rather than proceed to trial.

WHO IS ELIGIBLE FOR THE SETTLEMENT?

To be eligible to participate in this settlement, you must be a member of the class, or the estate or legal representative of a class member. The class is defined as:

> women who were prescribed Paxil® or Paxil CR™ in Canada and subsequently aborted, delivered, or miscarried children with congenital malformations after ingesting either drug while pregnant, family members who may make claims under *Family Compensation Legislation* following the death of, or injury to such children, children born alive to such women, and provincial and territorial governments who paid health care costs on their behalf.

SETTLEMENT TERMS

You can obtain a copy of the *Settlement Agreement* by contacting Class Counsel or the Claims Administrator at the addresses below. In summary, GSK agreed to pay an all-inclusive sum of $7,500,000 to settle the allegations in the lawsuit. This money is available to compensate class members, to pay provincial and territorial governments for health care costs they paid on behalf of class members, and to pay legal fees and expenses related to the prosecution of this class proceeding and the administration of the settlement.

HOW TO MAKE A CLAIM

Class members must submit a *Claim Form* and supporting documentation to the Claims Administrator at the address listed below before <Claims Deadline>. The Claims Officer will then determine each class member's entitlement to compensation based on that supporting documentation.

ADDITIONAL INFORMATION

This is not an advertisement or solicitation by a lawyer. The Court has approved the content of this notice, and it affects your legal rights. You should seek independent legal advice to consider your options. You can review additional documents related to the class proceeding at www.paxilbirthdefectsclassaction.ca. You may also call 1-877-400-1211 or e-mail inquiry@trilogyclassactions.ca with inquiries about the class proceeding and for further information on whether you are a class member and how you may participate further.

For more information about the lawsuit and/or to obtain a *Claim Form*, please contact Class Counsel at:

NAPOLI SHKOLNIK CANADA
1000 - 7 Avenue SW, Suite 400
Calgary, Alberta
T2P 5L5

Clint Docken KC | Casey R. Churko
Tel: (306) 540-2284
Fax: (639) 739-2223
cchurko@napolilaw.com

or contact the Claims Administrator at:

Paxil Birth Defects Class Action
c/o Trilogy Class Action Services
117 Queen Street, P.O. Box 1000
Niagara-on-the-Lake, Ontario
L0S 1J0
Tel: (877) 400-1211
Fax: (416) 342-1761
E-mail: claims@trilogyclassactions.ca

SCHEDULE B – Notice Plan for *Notice of Settlement Approval*

The *Notice of Settlement Approval* shall be given by the following means:

1. The Notice Provider shall send a copy of the *Notice of Settlement Approval* by mail or email to individuals who identified themselves as Class Members. Class Counsel shall provide the Notice Provider with a list of known Class Members.

2. The Notice Provider shall deliver the *Notice of Settlement Approval* to Health Authorities.

3. The Notice Provider shall deliver the *Notice of Settlement Approval* to the offices of the provincial and territorial public guardians and trustees.

4. The Notice Provider shall post a copy of the *Notice of Settlement Approval* at www.paxilbirthdefectsclassaction.ca.

5. The Notice Provider shall distribute notice to potential Class Members by way of Google advertisements.

6. Notice may be distributed in any other suitable manner which the Parties may agree to, provided that the total cost of giving *Notice of Settlement Approval* shall not exceed $27,500.

7. Class Counsel may supplement this Notice Plan in any other lawful means and at their own cost.

SCHEDULE C – *Settlement Approval Order*

Clerk's Stamp

Clerk's Stamp

ACTION NUMBER	1201-12838
COURT	COURT OF KING'S BENCH OF ALBERTA
JUDICIAL CENTRE	CALGARY
PLAINTIFFS	FIONA SINGH and MUZAFFAR HUSSAIN by his litigation representative FIONA SINGH
DEFENDANTS	GLAXOSMITHKLINE INC. GLAXOSMITHKLINE LLC and GLAXOSMITHKLINE PLC.

Brought under the Class Proceedings Act

DOCUMENT	**ORDER**
ADDRESS FOR SERVICE AND CONTACT INFORMATION OF PARTY FILING THIS DOCUMENT	NAPOLI SHKOLNIK CANADA 1000 – 7 Avenue SW, Suite 400 Calgary, Alberta T2P 5L5 **Clint Docken, K.C. | Casey R. Churko** Tel: (403) 619-3612 Fax: (639) 739-2223

DATE ORDER WAS PRONOUNCED:	September 24th, 2024
JUDGE WHO MADE THE ORDER:	Hon. Justice E.J. Sidnell

ORDER
(Settlement Approval)

UPON THE APPLICATION of the Plaintiffs:

AND UPON READING the *Settlement Agreement* and the *Schedules* thereto, which are attached to this Order as Schedule "1"

AND ON HEARING the submissions of counsel for the Plaintiffs and of counsel for the Defendants;

AND UPON BEING ADVISED that notice of this Settlement Approval Hearing was provided by the Claims Administrator pursuant to the terms of the *Order (Settlement Approval Hearing Notice)* pronounced June 5th, 2024 and filed June 10th, 2024;

AND UPON HAVING CONSIDERED all materials filed and used at the hearing;

IT IS HEREBY ORDERED:

1. The *Settlement Agreement* attached to this *Order* as Schedule "1", including all of the *Schedules* thereto, is incorporated by reference into and forms part of this Order and unless otherwise indicated herein, for the purposes of this *Order*, the definitions set out in the *Settlement Agreement* apply to and are incorporated into this *Order*.

2. The *Settlement Agreement*, including all of the *Schedules* thereto, is fair, reasonable, and in the best interests of the Class and is hereby approved and is binding on Class Members, the Releasors, and the Defendants pursuant to the *Class Proceedings Act*, SA 2003 c C-16.5, s 35 and shall be implemented in accordance with its terms. The steps taken by the Notice Provider to notify Class Members of the Settlement Approval Hearing are deemed reasonable and appropriate.

3. The *Notice of Settlement Approval*, in a substantially similar form to that attached as Schedule "A" to the *Settlement Agreement*, shall be distributed pursuant to the Notice Plan for *Notice of Settlement Approval*, attached as Schedule "B" to the *Settlement Agreement*, and such distribution is approved by this Court as being reasonable notice of the settlement and the terms of the *Settlement Agreement* in accordance with the requirements of the *Class Proceedings Act*.

4. The Claims Administrator may be paid up to $180,000 without further Court approval for Administration Costs (excluding its expenses and applicable taxes). If the Administration Costs of the Claims Administrator exceed $180,000 (excluding its expenses and applicable taxes), further amounts may be payable from the Compensation Fund on further application to, and with the approval of, the Court. Any work required of the Claims Administrator that is not part of its core duties in relation to the Distribution Protocol may be billed at the following hourly rates: $150 for translations; $325 for senior management; $155 for information technology; $155 for project management; and $65 for administrative duties.

5. The Defendants shall have no responsibility or liability, under any circumstances, for any additional or further payments as set out in the *Settlement Agreement*, including in relation to the settlement, Class Proceeding, or discontinuance of any individual actions of the Class Members pertaining to the subject matter of the Class Proceeding.

6. Any and all claims, whether direct, subrogated, or otherwise, that a Releasor or a Health Insurer may otherwise have had against the Releasees, Plaintiffs, or any Class Member, and whether arising by

statute, equity, or at law, is hereby and forever released and discharged, and the Releases as outlined in the *Settlement Agreement*, including in Appendix "A", provided by the Releasors and the Health Insurers (to the extent that Health Insurers may release such claims under their respective health care costs recovery legislation) are approved by this Court as being fair and reasonable and shall be binding on Class Members who have not opted out and the Health Insurers.

7. The Honorarium for the Representative Plaintiff's extraordinary service to the Class, being $50,000, is hereby approved. Payment of this amount to the Representative Plaintiff is authorized as a disbursement to be paid from the Settlement Fund.

8. The Class Counsel Fees and Class Counsel Disbursements plus applicable taxes thereon is approved for work done on behalf of the Class from the commencement of the Class Proceeding (and not before) to the Effective Date. The method for determining Lawyers' Fees is approved for work done and to be done on behalf of Eligible Claimants. The Class Counsel Fees, Class Counsel Disbursements, and Lawyers' Fees are approved only with respect to this proceeding and no other.

9. The appointment of Trilogy Class Action Services as the Claims Administrator, whose responsibilities shall include but may not be limited to (a) administering the Distribution Protocol in collaboration with the Claims Officer, (b) accepting and maintaining documents sent from Class Members, including *Claim Forms* and other documents relating to Claims administration, (c) administering the Settlement Fund and Compensatory Payments, and (d) all other responsibilities designated to the Claims Administrator in the *Settlement Agreement*, is hereby approved. The Claims Administrator will provide Class Counsel and the Defendants with any information or documents that Class Counsel or the Defendants request concerning the administration of the settlement including details of distribution.

10. The appointment of a Claims Officer, to be agreed to by the Parties or further Order of this Court and whose responsibilities shall include but not be limited to (a) reviewing medical records of the Claimants, (b) determining whether a Claimant Child was born with a Qualifying Congenital Malformation, (c) identifying the category in the Distribution Protocol applicable to the Qualifying Congenital Malformation, and (d) assigning a points value within the ranges set out in the Distribution Protocol, is hereby approved.

11. The Claims Deadline shall be 90 days from the publication of the *Notice of Settlement Approval*. A Class Member, whether represented or unrepresented, will be at liberty to apply to the Court to extend the Claims Deadline or the Claims Perfection Deadline for up to 60 days, so long as such application is made before the Claims Deadline or Claims Perfection Deadline and the Class Member provides notice of the application to the Claims Administrator, Class Counsel, and counsel for the Defendants. Such application will be unnecessary if Class Counsel, the Claims Administrator, and counsel for the Defendants each agree to extend the Claims Deadline, and where the Class Member explains the need for the extension to the satisfaction of both Class Counsel and counsel for the Defendants.

12. The Distribution Protocol attached as Schedule "D" to the *Settlement Agreement* is hereby approved. The determination of the validity of the Claims submitted by Class Members shall be made by the Claims Administrator and may be appealed as outlined in the *Settlement Agreement* to the Court of King's Bench within 30 days of the Claims Administrator's decision. The appeal shall be determined by Justice E. Jane Sidnell, or her designate, on the basis of written submissions only. All submissions will be provided to the Defendants. The appeal decision shall be final and binding, and shall not be subject to any further appeal. Disputes, other than eligibility and assessment of Compensatory Payments, will be determined pursuant to the laws of Alberta and Canada, and where necessary will be adjudicated by the case management justice in the Court of King's Bench.

13. Without affecting the finality of this *Order*, this Court shall retain exclusive continuing jurisdiction over the settlement process and the Parties thereto, including for all matters relating to supervising, administering, implementing, enforcing, and interpreting the *Settlement Agreement* and the Claims and Distribution Protocol thereunder, the enforcement of this *Order*, and all proceedings related to the *Settlement Agreement*, both before and after the approval of the *Settlement Agreement* until the settlement referred to therein becomes final and is no longer subject to appeal. The Parties may apply to this Court for further direction, if necessary, in respect of the implementation and administration of the *Settlement Agreement* and the Distribution Protocol. This Class Proceeding is otherwise dismissed and all the Claims of the Class Members as against the Defendants relating to the Allegations are extinguished upon distribution of the Compensation Fund.

CLERK OF THE COURT OF
KING'S BENCH OF ALBERTA

APPROVED as to form and content as the Order granted:

Napoli Shkolnik Canada
1900-144 4th Avenue SW
Calgary, Alberta
T2P 3N4

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CASEY R. CHURKO
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Per:

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RANDY SUTTON
Counsel for the Defendants,
GlaxoSmithKline Inc.,
GlaxoSmithKline LLC, and
GlaxoSmithKline plc

Per:

SCHEDULE D – Distribution Protocol

1. All capitalized terms used in this schedule have the same meaning as in the *Settlement Agreement*.

Process to Advance a Claim

2. A Class Member who wishes to receive benefits pursuant to the settlement of this Class Proceeding must provide the Claims Administrator with a *Claim Form* (Appendix 1) before the Claims Deadline.

3. Mailed or couriered *Claim Forms* received after the Claims Deadline but post marked or deposited with the courier on or before the Claims Deadline will be deemed received on the post marked date or the date deposited with the courier.

4. E-mailed or faxed *Claim Forms* will be deemed received on the date received by the Claims Administrator

Determination of Eligibility

5. To receive a Compensatory Payment, a Claimant must satisfy the Claims Administrator that he or she is an Eligible Claimant by the completion and submission of a valid *Claim Form* with related medical and pharmacy records.

6. To be eligible for compensation, the Claimant Mother, Claimant Child, or their legal or estate representative must satisfy the Claims Officer that:

(a) Neither the Claimant Mother or Claimant Child:

i. had a cardiovascular birth defect with no other Qualifying Congenital Malformation(s); and

ii. was a resident of the Province of British Columbia prior to February 3, 2006 when they were prescribed Paxil® or Paxil CR™;

(b) The records described below confirm that the Claimant Mother of the Claimant Child was prescribed branded (and not generic) Paxil® or Paxil CR™ (**Paxil**) in Canada.

(c) Paxil was dispensed to the Claimant Mother during the First Trimester of pregnancy.

(d) The prescription for Paxil referred to in paragraph 6(b) was dispensed:

i. prior to February 3, 2006, in which case no percentage reduction will be applied to any Compensatory Payment;

ii. between February 3, 2006 and February 3, 2007, in which case a reduction of 50% will be applied to any Compensatory Payment; or

iii. February 3, 2007 or later, in which case, the Claimant will not be eligible for compensation.

(e) The Claimant Child was born alive and subsequently diagnosed with a birth defect that constitutes a Qualifying Congenital Malformation.

Qualifying Congenital Malformations

7. Qualifying Congenital Malformations are limited to the following exhaustive list:

(a) Anencephaly;

(b) Spina bifida;

(c) Encephalocele;

(d) Craniosynostosis;

(e) Cleft lip;

(f) Cleft palate;

(g) Structural cardiovascular defects;

(h) Diaphragmatic hernia;

(i) Gastroschisis;

(j) Omphalocele;

(k) Hypospadias;

(l) Undescended testes; and

(m) Club foot.

8. To establish a diagnosis of a Qualifying Congenital Malformation, and the severity and/or necessary medical intervention to treat or resolve same, the Class Member must provide supporting medical documentation, which may include medical records, clinical records, hospital records, pathology records, laboratory records, and similar records. The records may be supplemented by a sworn affidavit of the Class Member's health care provider that confirms the diagnosis, treatment, and nature of the injury.

Reduction in Compensation for Confounding Factors

9. The Claims Officer will have the discretion to reduce the points value assigned to Claims of eligible Class Members on a percentage basis up to a maximum of 50% where there are confounding factors from the list below that, in the opinion of the Claims Officer based on his or her review of the available medical records, may have caused or contributed to the Qualifying Congenital Malformation(s) or other underlying health issues that impacted the Class Member's health, care, and/or quality of life, being:

(a) genetic diagnoses of the kind associated with one or more of the Qualifying Congenital Malformations;

(b) smoking, alcohol and/or illicit drug use of the mother during pregnancy;

(c) maternal age;

(d) pre-gestational diabetes;

(e) metabolic disorders during pregnancy;

(f) body mass index outside of the normal range (18.5 to 25);

(g) significant physical trauma experienced during pregnancy; and/or

(h) exposures to medications or chemicals during pregnancy that are associated with birth defects, as determined by the Claims Officer.

10. Additionally, and to account for the resolution of class action litigation commenced in British Columbia concerning the use of Paxil during pregnancy, and the resulting compensation received by class members diagnosed with a cardiac defect, a percentage reduction may be applied where the Class Member resided in British Columbia and the Claimant Child was diagnosed with a cardiovascular defect in addition to at least one other Qualifying Congenital Malformation to reflect that any claim by these Class Members for a cardiovascular defect was previously settled.

Evidence of Prescription and Use

11. To establish the prescription and ingestion of Paxil necessary to being an Eligible Claimant, the Class Member must provide either prescription records, medical records, hospital records, clinical records, pharmacy records, receipts and/or insurance records (the **Records**) that show that brand name Paxil distributed by GSK was prescribed or dispensed to the Class Member in Canada during their First Trimester of pregnancy.

12. Where the records described in Item #11 are unavailable, and there is therefore no Record confirming that the Class Member was prescribed and/or ingested branded Paxil during the First Trimester, then the following may be considered by the Claims Administrator as acceptable evidence of the Class Member's prescription and use of branded Paxil:

(a) A signed letter from the Class Member's physician who treated the Class Member at the material time, which includes current contact information, confirming that, to the best of his or her recollection, branded Paxil was prescribed to the Class Member, or that the treating physician was otherwise aware that the Class Member was ingesting branded Paxil, during the First Trimester of the pregnancy; and

(b) An affidavit sworn by the Class Member's physician who treated the Class Member at the material time explaining that:

i. a search of the treating physician's records was undertaken and no Record confirming proof of ingestion or use of branded Paxil could be located;

ii. the physician treated the Class Member at the material time;

iii. based on the review of the treating physician, there is no Record that contradicts the treating physician's recollection with respect to the timing of use and branded Paxil being prescribed or ingested;

iv. to the best of the treating physician's knowledge, there is no reason to doubt the accuracy of his or her recollection with respect to the Class Member's prescription or use of Paxil during the First Trimester;

v. his or her memory should be considered sufficient in the absence of Records; and

vi. the treating physician agrees to comply with any further questions or audits conducted by the Claims Administrator with respect to statements that the Class Member was prescribed or ingested branded Paxil during the First Trimester.

13. A statement by the Class Member that Paxil was ingested during the First Trimester of pregnancy is not sufficient unless the physician described in Item #12 is deceased or has ceased to practice and if medical records, including hospital records or physician notes, state that no medications were taken during pregnancy, the Class Member will not be eligible for compensation.

14. Evidence of prescription or purchase of Paxil will also be considered evidence of ingestion of the drug.

15. Where, after the first date of generic entry of paroxetine occurred, supporting medical documents reference only "paroxetine" and there is no indication in the evidence provided that Paxil, as opposed to generic paroxetine, was prescribed, then the Class Member will not be eligible for compensation.

16. For greater certainty, this settlement is designed to compensate for the use of branded Paxil distributed by GSK only, and not generic paroxetine.

Eligibility and Compensation to the Discretion of the Claims Administrator and Claims Officer

17. Whether eligibility can be accurately determined through the *Claim Form* and the Records provided will be to the sole discretion of the Claims Administrator and Claims Officer.

18. It is the responsibility of the Class Member, or his/her legal or estate representative, to provide sufficient evidence to support his/her Claim. Any fees or charges incurred by the Class Member with respect to filing his/her Claim are the responsibility of the Class Member.

19. The determination of the validity of the Claims submitted by Class Members shall be made by the Claims Administrator and may be appealed to the Court of King's Bench within 30 days of the Claims Administrator's decision. The appeal shall be determined by Justice E. Jane Sidnell, or her designate, on the basis of written submissions only. The appeal decision shall be final and binding, and shall not be subject to any further appeal.

20. The Claims Officer shall review each *Claim Form* and determine whether the individual is an Eligible Claimant.

21. If a person is acting on behalf of the Claimant Mother or Claimant Child, the Claims Administrator shall require verification that the person has the legal authority to do so, and if the person is a lawyer in any jurisdiction, that he or she is licensed to practice law in a Canadian province or territory.

22. Upon the request of counsel to the Plaintiffs or Defendants, or the Claims Officer, or at the discretion of the Claims Administrator, the Parties agree that the Claims Administrator may conduct an audit or such other review to confirm the veracity of (a) the Records, (b) the treating physician's letter and accompanying affidavit, and/or (c) the absence of the Records and explanation for that absence. The Claims Administrator and Claims Officer may revoke any findings with respect to eligibility and/or adequate evidence of the Class Member's claim as a result of the Claims Administrator's review or audit.

Distribution of Settlement Fund

23. The Claims Administrator shall distribute the Settlement Fund in accordance with the terms of the *Settlement Agreement* and based on the determinations of the Claims Officer.

Damages – Category Assessments

24. A Class Member's entitlement to a Compensatory Payment under this Distribution Protocol shall be determined by the Claims Officer as outlined herein.

25. Compensatory Payments will be assessed by the Claims Officer through a review of the medical records and other documents submitted on behalf of the Claimant Mother, Claimant Child, or from the submissions of a physician applying the following grid:

<u>Cardiac Malformations</u>: atrial septal defect excluding patent foramen ovale; atrioventricular septal defect; coarctation of the aorta; transposition of the great vessels; hypoplastic left heart syndrome; pulmonary atresia; pulmonary stenosis; tetralogy of fallot; total anomalous pulmonary venous return; tricuspid atresia; truncus arteriosus; and ventricular septal defect.		
A.	No procedure, only diagnosis and ongoing monitoring	5 to 10

B.	Non-surgical treatment(s) to repair or treat the malformation(s)	10 to 20
C.	One surgery to repair or treat the malformation(s)	20 to 60
D.	Multiple surgeries to repair or treat the malformation(s)	40 to 100

Neural Tube Defect Malformations: anencephaly; spina bifida; and encephalocele		
A.	No procedure, only diagnosis and ongoing monitoring	5 to 10
B.	Non-surgical treatment(s) to repair or treat the malformation(s)	10 to 20
C.	One surgery to repair or treat the malformation(s)	20 to 50
D.	Multiple surgeries to repair or treat the malformation(s)	40 to 75

Skeletal Malformations: club foot		
A.	No procedure, only diagnosis and ongoing monitoring	5 to 10
B.	Non-surgical treatment(s) to repair or treat the malformation(s)	10 to 15
C.	One surgery to repair or treat the malformation(s)	15 to 30
D.	Multiple surgeries to repair or treat the malformation(s)	30 to 50

Abdominal Malformations: gastroschisis; omphalocele; and diaphragmatic hernia **Urinary/Genital Malformations: undescended testes and hypospadias**		
A.	No procedure, only diagnosis and ongoing monitoring	5 to 10
B.	Non-surgical treatment(s) to repair or treat the malformation(s)	10 to 15
C.	One surgery to repair or treat the malformation(s)	15 to 20
D.	Multiple surgeries to repair or treat the malformation(s)	20 to 35

Craniofacial Malformations: cleft lip; cleft palate; and craniosynostosis.		
A.	No procedure, only diagnosis and ongoing monitoring	1 to 5
B.	Non-surgical treatment(s) to repair or treat the malformation(s)	5 to 10
C.	One surgery to repair or treat the malformation(s)	20 to 30

D.	Multiple surgeries to repair or treat the malformation(s)	30 to 60

26. The Claims Officer will identify the categories within which each Class Member's Claim falls and assign a points value within the range identified. Where a Class Member has more than one malformation, he or she will be awarded a points value respecting each category into which the Claim falls.

27. In determining the points value within the range, the Claims Officer will consider the following criteria in relation to the congenital malformations and the Claimant Child's medical condition:

A. Severity of malformation(s);
B. Duration and complexity of treatments;
C. Likelihood of future complications;
D. Likelihood of future medical interventions;
E. Likelihood of future medical/non-medical care; and
F. Likelihood of vocational impairment.

28. Each eligible Claimant Mother of a Class Member born alive with a Qualifying Congenital Malformation will be entitled to 25% of the points that the eligible Claimant Child is entitled to under this heading in full and complete satisfaction of her own Claim and the claims of any other Family Members.

General

29. The Claims Officer will seek to follow the processes outlined herein, but the Claims Officer may also establish further processes for the management or the determination of the Claims so as to ensure a fair, just, and timely determination of the Claims on the merits, and consistency in the application of this *Settlement Agreement*, and may implement such revisions upon approval by the Court, after providing 15 days' notice to the Parties.

30. The Claims Officer may at any time request further information, via the Claims Administrator, from the Class Member if the Claims Officer believes such information is necessary and available to validate the Claim, including as it pertains to ambiguities or inconsistencies in the Claim.

31. If the Class Member has legal counsel, all inquiries or requests will be sent to his/her lawyer. If the Claims Administrator does not receive the additional information requested or responding answers within 90 days after advising the Class Member of the deficiency or request, the Claim shall be assessed on the basis of the material provided by the Class Member.

32. The Claims Officer may consider the materials provided whether or not such materials would be admissible in a court of law. The Claims Officer may grant extensions of the time to provide materials on the written request of a Claimant; provided that all documentation respecting Claims shall be submitted on or before the Claims Perfection Deadline, and the Claims administration process shall be completed within a further 60 days thereafter.

33. The Claims Officer shall make best efforts to adjudicate a Claim and render a decision as to eligibility and point allocation within 60 days of receiving a Claim.

34. The Claims Administrator shall provide the decision of the Claims Officer in writing by way of a letter or email to the Class Member. If the Class Member has legal counsel, the decision will be sent to counsel directly.

35. Confirmation of eligibility and entitlement shall be determined on a balance of probabilities and common law principles. The determination of the validity of the Claims submitted by Class Members shall be made by the Claims Administrator and may be appealed as outlined in the *Settlement Agreement* to the Court of King's Bench within 30 days of the Claims Administrator's decision. The appeal shall be determined by Justice E. Jane Sidnell, or her designate, on the basis of written submissions only. The appeal decision

shall be final and binding, and shall not be subject to any further appeal. Disputes, other than eligibility and assessment of Compensatory Payments, will be determined pursuant to the laws of Alberta and Canada, and where necessary will be adjudicated by the case management justice in the Court of King's Bench.

Distribution of Compensation Fund

36. Compensatory Payments to Class Members shall be paid from the Compensation Fund on a pro-rata basis based on the number of points. All Claims will be adjudicated and finally determined before any amounts for Compensatory Payments are paid pursuant to the *Settlement Agreement*.

37. Compensatory Payments will not be paid until the Claims Administrator has satisfied itself of the adequacy and veracity of the evidence and documents provided by all Class Members in support of their Claims. In the event that Compensatory Payments are paid and the Parties subsequently learn that the Records or other supporting evidence of a Class Member's Claim were misrepresented or fraudulent, the Defendants and Claims Officer reserve all rights and remedies to recover the entirety of the Compensatory Payment at issue.

38. Lawyers' Fees will be paid as and when Compensatory Payments are made to Eligible Claimants from the Compensation Fund. Subject to section 8.5 of the *Settlement Agreement*, the Claims Administrator shall pay to Class Counsel:

(a) 35% of the Compensatory Payments made to Class Members they represent;

(b) 10% of the Compensatory Payments made to Eligible Claimants who are represented by other lawyers who executed retainer agreements with Class Members before the *Notice of Settlement Approval Hearing* is given;

(c) 25% of the Compensatory Payments made to any Eligible Claimants who are represented by other lawyers who executed retainer agreements with Class Members after the *Notice of Settlement Approval Hearing* is given; and

(d) 15% of Compensatory Payments that are made to Eligible Claimants who are unrepresented.

The amount of the combined Class Counsel Fees and Lawyers' Fees (including disbursements and taxes on Lawyers' Fees but not Class Counsel Fees) will not exceed 33.33% of the Settlement Fund. Lawyers' Fees (but not the Class Counsel Fees) will be proportionately reduced if the amount of the combined Class Counsel Fees and Lawyers' Fees (including disbursements and taxes on Lawyers' Fees but not Class Counsel Fees) otherwise determined herein would exceed 35% of the Settlement Fund plus interest thereon.

39. Within 7 days of the Effective Date, the Claims Administrator shall pay Health Insurers CDN $525,000 out of the Settlement Fund for healthcare costs recovery in full and final satisfaction of any and all claims they have respecting any and all Class Members, provided that each signs full and final releases in forms that are satisfactory to each Health Insurer. Health Insurers shall thereafter have no role in the Distribution Protocol

40. Distribution of payments to Class Members (other than the Honorarium), will not commence until after all Claims have been determined or adjudicated.

SCHEDULE E - *CLAIM FORM*

Paxil® and Paxil CR™ Congenital Malformations
Canadian Class Action Settlement With GlaxoSmithKline

1. If you were born with one or more congenital malformations to a mother who was prescribed Paxil® or Paxil CR™ for use in pregnancy, and used Paxil® or Paxil CR™ during the pregnancy or are the litigation or other guardian of the child, please provide the following information:

_____ _____ _____
First Name (Child) MI Last Name (Child)

_____/_____/_____ _____
DOB (dd/mm/yyyy) Social Insurance Number

_____ _____ _____ _____
Address City Province Postal Code

_____ _____
Best Contact Number Email

2. If you are the mother of a child who was diagnosed with one or more congenital malformations after you were prescribed Paxil® or Paxil CR™ and you used either drug during the pregnancy, please provide the following information:

_____ _____ _____
First Name (Mother) MI Last Name (Mother)

_____/_____/_____ _____
DOB (dd/mm/yyyy) Social Insurance Number

_____ _____ _____ _____
Address City Province Postal Code

_____ _____
Best Contact Number Email

3. Provide details of when you were prescribed Paxil® and Paxil CR™, when Paxil® and Paxil CR™ were dispensed and when you ingested Paxil® and Paxil CR™. Please provide records supporting the prescription or dispensation of Paxil® and Paxil CR™.

Date Started: _____ Date Stopped: _____

4. Provide the date that your child who is making a Claim for a congenital malformation was born: _____

5. Provide the date of the commencement of your last menstrual period prior to the period of pregnancy: _____

6. Select for the congenital malformation(s) for which the Claim is made:

Malformation	Specific Injuries
☐ Cardiac	Structural cardiac congenital malformations, including: ☐ atrial septal defect excluding patent foramen ovale ☐ atrioventricular septal defect ☐ coarctation of the aorta ☐ transposition of the great vessels ☐ hypoplastic left heart syndrome ☐ pulmonary atresia ☐ pulmonary stenosis ☐ tetralogy of fallot ☐ total anomalous pulmonary venous return ☐ tricuspid atresia ☐ truncus arteriosus ☐ ventricular septal defect
☐ Craniofacial	☐ cleft lip and/or palate ☐ craniosynostosis
☐ Neural tube	☐ anencephaly ☐ spina bifida ☐ encephalocele

☐ Abdominal

- ☐ gastroschisis
- ☐ omphalocele
- ☐ diaphragmatic hernia

☐ Skeletal

- ☐ club foot

☐ Urinary / genital

- ☐ undescended testes
- ☐ hypospadias

7. Provide the name and address for any physician, hospital, or other healthcare professional or institution who treated the child for any condition listed above, with dates of treatment if known:

Provider	Address	Dates of Treatment

8. Has the child had surgery for any of the conditions listed above?

☐ Yes ☐ No

i. If the child has had surger(ies) please list below the type of surgery, hospital and date.

Type of Surgery	Facility/Hospital	Dates of Surgeries

9. Describe and provide supporting documentation regarding the likelihood of future medical interventions, if any, arising from the congenital malformation:

10. Describe and providing supporting documentation, regarding any vocational impairment, if any, arising from the congenital malformation.

11. Describe and provide supporting documentation which speaks to the likelihood of potential future complications, if any, arising from the congenital malformation.

12. The undersigned hereby consent(s) to the disclosure of the information contained herein to the extent necessary to process this Claim for Compensatory Benefits. Each person signing below agrees to cooperate with the Claims Administrator and Claims Officer and to provide any necessary medical record authorizations and releases for the Claims Officer to gather information needed to substantiate or audit the Claim. Each person signing below acknowledges and understands that this *Claim Form* is an official Court document approved by the Court that presides over the settlement, and that submitting it to the Claims Officer is equivalent to filing it with a court. After reviewing the information which has been supplied on this form, each person declares under penalty of perjury that the information provided in this form is true and correct to the best of his/her knowledge, information and belief.

Signature of Claimant Child (if an adult) (dd/mm/yyyy)

Signature of Mother or Litigation or other Guardian (dd/mm/yyyy)

SCHEDULE 2 – DISTRIBUTION PROTOCOL

Distribution Protocol – Singh v. GlaxoSmithKline Inc.

1. All capitalized terms used in this schedule have the same meaning as in the *Settlement Agreement*.

Process to Advance a Claim

2. A Class Member who wishes to receive benefits pursuant to the settlement of this Class Proceeding must provide the Claims Administrator with a *Claim Form* (Appendix 1) before the Claims Deadline.

3. Mailed or couriered *Claim Forms* received after the Claims Deadline but post marked or deposited with the courier on or before the Claims Deadline will be deemed received on the post marked date or the date deposited with the courier.

4. E-mailed or faxed *Claim Forms* will be deemed received on the date received by the Claims Administrator

Determination of Eligibility

5. To receive a Compensatory Payment, a Claimant must satisfy the Claims Administrator that he or she is an Eligible Claimant by the completion and submission of a valid *Claim Form* with related medical and pharmacy records.

6. To be eligible for compensation, the Claimant Mother, Claimant Child, or their legal or estate representative must satisfy the Claims Officer that:

a) Neither the Claimant Mother or Claimant Child:
    i. had a cardiovascular birth defect with no other Qualifying Congenital Malformation(s); and
    ii. was a resident of the Province of British Columbia prior to February 3, 2006 when they were prescribed Paxil® or Paxil CR™;
b) The records described below confirm that the Claimant Mother of the Claimant Child was prescribed branded (and not generic) Paxil® or Paxil CR™ (**Paxil**) in Canada.
c) Paxil was dispensed to the Claimant Mother during the First Trimester of pregnancy.
d) The prescription for Paxil referred to in paragraph 6(b) was dispensed:
    i. prior to February 3, 2006, in which case no percentage reduction will be applied to any Compensatory Payment;
    ii. between February 3, 2006 and February 3, 2007, in which case a reduction of 50% will be applied to any Compensatory Payment; or
    iii. February 3, 2007 or later, in which case, the Claimant will not be eligible for compensation.
e) The Claimant Child was born alive and subsequently diagnosed with a birth defect that constitutes a Qualifying Congenital Malformation.

Qualifying Congenital Malformations

7. Qualifying Congenital Malformations are limited to the following exhaustive list:

(a) Anencephaly;
(b) Spina bifida;
(c) Encephalocele;
(d) Craniosynostosis;
(e) Cleft lip;
(f) Cleft palate;
(g) Structural cardiovascular defects;
(h) Diaphragmatic hernia;
(i) Gastroschisis;
(j) Omphalocele;
(k) Hypospadias;
(l) Undescended testes; and
(m) Club foot.

8. To establish a diagnosis of a Qualifying Congenital Malformation, and the severity and/or necessary medical intervention to treat or resolve same, the Class Member must provide supporting medical documentation, which may include medical records, clinical records, hospital records, pathology records, laboratory records, and similar records. The records may be supplemented by a sworn affidavit of the Class Member's health care provider that confirms the diagnosis, treatment, and nature of the injury.

Reduction in Compensation for Confounding Factors

9. The Claims Officer will have the discretion to reduce the points value assigned to Claims of eligible Class Members on a percentage basis up to a maximum of 50% where there are confounding factors from the list below that, in the opinion of the Claims Officer based on his or her review of the available medical records, may have caused or contributed to the Qualifying Congenital Malformation(s) or other underlying health issues that impacted the Class Member's health, care, and/or quality of life, being:

(a) genetic diagnoses of the kind associated with one or more of the Qualifying Congenital Malformations;
(b) smoking, alcohol and/or illicit drug use of the mother during pregnancy;
(c) maternal age;
(d) pre-gestational diabetes;
(e) metabolic disorders during pregnancy;
(f) body mass index outside of the normal range (18.5 to 25);
(g) significant physical trauma experienced during pregnancy; and/or
(h) exposures to medications or chemicals during pregnancy that are associated with birth defects, as determined by the Claims Officer.

10. Additionally, and to account for the resolution of class action litigation commenced in British Columbia concerning the use of Paxil during pregnancy, and the resulting compensation received by class members diagnosed with a cardiac defect, a percentage reduction may be applied where the Class Member resided in British Columbia and the Claimant Child was diagnosed with a cardiovascular defect in addition to at least one other Qualifying Congenital Malformation to reflect that any claim by these Class Members for a cardiovascular defect was previously settled.

Evidence of Prescription and Use

11. To establish the prescription and ingestion of Paxil necessary to being an Eligible Claimant, the Class Member must provide either prescription records, medical records, hospital records, clinical records, pharmacy records, receipts and/or insurance records (the **Records**) that show that brand name Paxil distributed by GSK was prescribed or dispensed to the Class Member in Canada during their First Trimester of pregnancy.

12. Where the records described in Item #11 are unavailable, and there is therefore no Record confirming that the Class Member was prescribed and/or ingested branded Paxil during the First Trimester, then the following may be considered by the Claims Administrator as acceptable evidence of the Class Member's prescription and use of branded Paxil:

(a) A signed letter from the Class Member's physician who treated the Class Member at the material time, which includes current contact information, confirming that, to the best of his or her recollection, branded Paxil was prescribed to the Class Member, or that the treating physician was otherwise aware that the Class Member was ingesting branded Paxil, during the First Trimester of the pregnancy; and

(b) An affidavit sworn by the Class Member's physician who treated the Class Member at the material time explaining that:

i. a search of the treating physician's records was undertaken and no Record confirming proof of ingestion or use of branded Paxil could be located;

ii. the physician treated the Class Member at the material time;

iii. based on the review of the treating physician, there is no Record that contradicts the treating physician's recollection with respect to the timing of use and branded Paxil being prescribed or ingested;

iv. to the best of the treating physician's knowledge, there is no reason to doubt the accuracy of his or her recollection with respect to the Class Member's prescription or use of Paxil during the First Trimester;

v. his or her memory should be considered sufficient in the absence of Records; and

vi. the treating physician agrees to comply with any further questions or audits conducted by the Claims Administrator with respect to statements that the Class Member was prescribed or ingested branded Paxil during the First Trimester.

13. A statement by the Class Member that Paxil was ingested during the First Trimester of pregnancy is not sufficient unless the physician described in Item #12 is deceased or has ceased to practice and if medical records, including hospital records or physician notes, state that no medications were taken during pregnancy, the Class Member will not be eligible for compensation.

14. Evidence of prescription or purchase of Paxil will also be considered evidence of ingestion of the drug.

15. Where, after the first date of generic entry of paroxetine occurred, supporting medical documents reference only “paroxetine” and there is no indication in the evidence provided that Paxil, as opposed to generic paroxetine, was prescribed, then the Class Member will not be eligible for compensation.

16. For greater certainty, this settlement is designed to compensate for the use of branded Paxil distributed by GSK only, and not generic paroxetine.

Eligibility and Compensation to the Discretion of the Claims Administrator and Claims Officer

17. Whether eligibility can be accurately determined through the *Claim Form* and the Records provided will be to the sole discretion of the Claims Administrator and Claims Officer.

18. It is the responsibility of the Class Member, or his/her legal or estate representative, to provide sufficient evidence to support his/her Claim. Any fees or charges incurred by the Class Member with respect to filing his/her Claim are the responsibility of the Class Member.

19. The determination of the validity of the Claims submitted by Class Members shall be made and communicated by the Claims Administrator and the Claims Officer and may be appealed to the Court of King’s Bench within 30 days of receiving the communication of the Claims Administrator’s decision. The appeal shall be determined by Justice E. Jane Sidnell, or her designate, on the basis of written submissions only. Appeals shall be initiated in the form attached to this Schedule 2.

20. The Claims Officer shall review each *Claim Form* and determine whether the individual is an Eligible Claimant.

21. Upon the request of counsel to the Plaintiffs or Defendants, or the Claims Officer, or at the discretion of the Claims Administrator, the Parties agree that the Claims Administrator may conduct an audit or such other review to confirm the veracity of (a) the Records, (b) the treating physician’s letter and accompanying affidavit, and/or (c) the absence of the Records and explanation for that absence. The Claims Administrator and Claims Officer may revoke any findings with respect to eligibility and/or adequate evidence of the Class Member’s claim as a result of the Claims Administrator’s review or audit and that decision is subject to appeal, under paragraph 19.

Distribution of Settlement Fund

22. The Claims Administrator shall distribute the Settlement Fund in accordance with the terms of the *Settlement Agreement* and based on the determinations of the Claims Officer.

Damages – Category Assessments

23. A Class Member’s entitlement to a Compensatory Payment under this Distribution Protocol shall be determined by the Claims Officer as outlined herein.

24. Compensatory Payments will be assessed by the Claims Officer through a review of the medical records and other documents submitted on behalf of the Claimant Mother, Claimant Child, or from the submissions of a physician applying the following grid:

<u>Cardiac Malformations</u>: atrial septal defect excluding patent foramen ovale; atrioventricular septal defect; coarctation of the aorta; transposition of the great vessels; hypoplastic left heart syndrome; pulmonary atresia; pulmonary stenosis; tetralogy of fallot; total anomalous pulmonary venous return; tricuspid atresia; truncus arteriosus; and ventricular septal defect.		
A.	No procedure, only diagnosis and ongoing monitoring	5 to 10
B.	Non-surgical treatment(s) to repair or treat the malformation(s)	10 to 20
C.	One surgery to repair or treat the malformation(s)	20 to 60
D.	Multiple surgeries to repair or treat the malformation(s)	40 to 100
<u>Neural Tube Defect Malformations</u>: anencephaly; spina bifida; and encephalocele		
A.	No procedure, only diagnosis and ongoing monitoring	5 to 10
B.	Non-surgical treatment(s) to repair or treat the malformation(s)	10 to 20
C.	One surgery to repair or treat the malformation(s)	20 to 50
D.	Multiple surgeries to repair or treat the malformation(s)	40 to 75
<u>Skeletal Malformations</u>: club foot		
A.	No procedure, only diagnosis and ongoing monitoring	5 to 10
B.	Non-surgical treatment(s) to repair or treat the malformation(s)	10 to 15
C.	One surgery to repair or treat the malformation(s)	15 to 30
D.	Multiple surgeries to repair or treat the malformation(s)	30 to 50
<u>Abdominal Malformations</u>: gastroschisis; omphalocele; and diaphragmatic hernia <u>Urinary/Genital Malformations</u>: undescended testes and hypospadias		
A.	No procedure, only diagnosis and ongoing monitoring	5 to 10
B.	Non-surgical treatment(s) to repair or treat the malformation(s)	10 to 15
C.	One surgery to repair or treat the malformation(s)	15 to 20
D.	Multiple surgeries to repair or treat the malformation(s)	20 to 35
<u>Craniofacial Malformations</u>: cleft lip; cleft palate; and craniosynostosis.		
A.	No procedure, only diagnosis and ongoing monitoring	1 to 5
B.	Non-surgical treatment(s) to repair or treat the malformation(s)	5 to 10

C.	One surgery to repair or treat the malformation(s)	20 to 30
D.	Multiple surgeries to repair or treat the malformation(s)	30 to 60

25. The Claims Officer will identify the categories within which each Class Member's Claim falls and assign a points value within the range identified. Where a Class Member has more than one malformation, he or she will be awarded a points value respecting each category into which the Claim falls.

26. In determining the points value within the range, the Claims Officer will consider the following criteria in relation to the congenital malformations and the Claimant Child's medical condition:

A. Severity of malformation(s);
B. Duration and complexity of treatments;
C. Likelihood of future complications;
D. Likelihood of future medical interventions;
E. Likelihood of future medical/non-medical care; and
F. Likelihood of vocational impairment.

27. Each eligible Claimant Mother of a Class Member born alive with a Qualifying Congenital Malformation will be entitled to 25% of the points that the eligible Claimant Child is entitled to under this heading in full and complete satisfaction of her own Claim and the claims of any other Family Members.

General

28. The Claims Officer will seek to follow the processes outlined herein, but the Claims Officer may also establish further processes for the management or the determination of the Claims so as to ensure a fair, just, and timely determination of the Claims on the merits, and consistency in the application of this *Settlement Agreement*, and may implement such revisions upon approval by the Court, after providing 15 days' notice to the Parties.

29. The Claims Officer may at any time request further information, via the Claims Administrator, from the Class Member if the Claims Officer believes such information is necessary and available to validate the Claim, including as it pertains to ambiguities or inconsistencies in the Claim.

30. If the Class Member has legal counsel, all inquiries or requests will be sent to his/her lawyer. If the Claims Administrator does not receive the additional information requested or responding answers within 90 days after advising the Class Member of the deficiency or request, the Claim shall be assessed on the basis of the material provided by the Class Member.

31. The Claims Officer may consider the materials provided whether or not such materials would be admissible in a court of law. The Claims Officer may grant extensions of the time to provide materials on the written request of a Claimant; provided that all documentation respecting Claims shall be submitted on or before the Claims Perfection Deadline, and the Claims administration process shall be completed within a further 60 days thereafter.

32. The Claims Officer shall make best efforts to adjudicate a Claim and render a decision as to eligibility and point allocation within 60 days of receiving a Claim.

33. The Claims Administrator shall provide the decision of the Claims Officer in writing by way of a letter or email to the Class Member. If the Class Member has legal counsel, the decision will be sent to counsel directly.

Confirmation of eligibility and entitlement shall be determined on a balance of probabilities and common law principles. The determination of the validity of the Claims submitted by Class Members shall be made by the Claims Administrator and may be appealed as outlined in the *Settlement Agreement* to the Court of King's Bench within 30 days of the Claims Administrator's decision. The appeal shall be determined by Justice E. Jane Sidnell, or her designate, on the basis of written submissions only. The appeal decision shall be final and binding, and shall not be subject to any further appeal. Disputes, other than eligibility and assessment of Compensatory Payments, will be determined pursuant to the laws of Alberta and Canada, and where necessary will be adjudicated by the case management justice in the Court of King's Bench.

Distribution of Compensation Fund

34. Compensatory Payments to Class Members shall be paid from the Compensation Fund on a pro-rata basis based on the number of points. All Claims will be adjudicated and finally determined before any amounts for Compensatory Payments are paid pursuant to the *Settlement Agreement*.

35. Compensatory Payments will not be paid until the Claims Administrator has satisfied itself of the adequacy and veracity of the evidence and documents provided by all Class Members in support of their Claims. In the event that Compensatory Payments are paid and the Parties subsequently learn that the Records or other supporting evidence of a Class Member's Claim were misrepresented or fraudulent, the Defendants and Claims Officer reserve all rights and remedies to recover the entirety of the Compensatory Payment at issue.

36. Lawyers' Fees will be paid as and when Compensatory Payments are made to Eligible Claimants from the Compensation Fund. Subject to section 8.5 of the *Settlement Agreement*, the Claims Administrator shall pay to Class Counsel:

- 35% of the Compensatory Payments made to Class Members they represent;
- 10% of the Compensatory Payments made to Eligible Claimants who are represented by other lawyers who executed retainer agreements with Class Members before the *Notice of Settlement Approval Hearing* is given;
- 25% of the Compensatory Payments made to any Eligible Claimants who are represented by other lawyers who executed retainer agreements with Class Members after the *Notice of Settlement Approval Hearing* is given; and
- 15% of Compensatory Payments that are made to Eligible Claimants who are unrepresented.

The amount of the combined Class Counsel Fees and Lawyers' Fees (including disbursements and taxes on Lawyers' Fees but not Class Counsel Fees) will not exceed 33.33% of the Settlement Fund. Lawyers' Fees (but not the Class Counsel Fees) will be proportionately reduced if the amount of the combined Class Counsel Fees and Lawyers' Fees (including disbursements and taxes on Lawyers' Fees but not Class Counsel Fees) otherwise determined herein would exceed 35% of the Settlement Fund plus interest thereon.

37. Within 7 days of the Effective Date, the Claims Administrator shall pay Health Insurers CDN $525,000 out of the Settlement Fund for healthcare costs recovery in full and final satisfaction of any and all claims they have respecting any and all Class Members, provided that each signs full and final releases in forms that are satisfactory to each Health Insurer. Health Insurers shall thereafter have no role in the Distribution Protocol

38. Distribution of payments to Class Members (other than the Honorarium), will not commence until after all Claims have been determined or adjudicated.

SCHEDULE TO DISTRIBUTION PROTOCOL

APPEAL FROM DECISION OF CLAIMS ADMINISTRATOR/CLAIMS OFFICER

ACTION NUMBER	1201-12838
COURT	COURT OF KING'S BENCH OF ALBERTA
JUDICIAL CENTRE	CALGARY
PLAINTIFFS	FIONA SINGH and MUZAFFAR HUSSAIN by his litigation representative FIONA SINGH
DEFENDANTS	GLAXOSMITHKLINE INC. GLAXOSMITHKLINE LLC and GLAXOSMITHKLINE PLC.

Paxil® and Paxil CR™ Congenital Malformations
Appeal from Canadian Class Action Settlement Claims Process
Pursuant to Paragraph 19 of the Distribution Protocol Approved by
Order Date September 24, 2024

NAME OF PARTY APPEALING: _____
YOUR ADDRESS: _____
_____
_____
_____

DATE ON WHICH THE DECISION WAS MADE: _____

WHAT IS THE REASON FOR YOUR APPEAL:

_____
_____
_____
_____
_____

DATE: _____
SIGNATURE OF PARTY APPEALING: _____

A COPY OF THIS APPEAL FORM SHOULD BE PROVIDED TO THE CLERK OF THE COURT OF KINGS BENCH WHO WILL PROVIDE IT TO THE HONOURABLE JUSTICE E. JANE SIDNELL AND TO THE LAWYERS FOR THE CLASS:

Napoli Shkolnik Canada
1900-144 4th Avenue SW
Calgary, Alberta, T2P 3N4
Attention: Casey R. Churko
Tel: (306) 540-2284 / Fax: (639) 739-2223 / Email: cchurko@caselaw.cc